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State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

July 1, 2010

TO: California Physicians Administering Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®)

FROM: Mark B. Horton, MD, MSPH
State Public Health Officer

SUBJECT: Continued Use of Japanese Encephalitis Virus Vaccine Inactivated
From July 1, 2010 – June 30, 2011

SUMMARY

Since July 1, 2006, California Health and Safety Code section 124172 provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances. The Secretary of the California Health and Human Services Agency has again granted a 12-month exemption to this restriction for Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®) from July 1, 2010, to June 30, 2011. This exemption will allow this vaccine to continue to be administered to children younger than 3 years old and pregnant women younger than 17 years of age. The exception was granted because of the dangers posed by JE virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California younger than 17 years of age seeking protection against JE. Physicians who wish to protect pregnant women 17 years and older against JE should instead consider use of the preservative-free JE vaccine (IXIARO®, manufactured by Intercell Biomedical and distributed by Novartis Vaccines and Diagnostics, Inc.).

JE Disease and Vaccine

JE, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005 major outbreaks of JE have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the JE virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of JE, while infection during pregnancy may cause miscarriage. There is currently no treatment for JE.

The U.S. Food and Drug Administration (FDA) has licensed two vaccines against JE for use in the United States:

1) Japanese Encephalitis Virus Vaccine Inactivated, whose trade name is JE-VAX®. It is manufactured in Japan by The Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by sanofi pasteur, Inc.

Japanese Encephalitis Virus Vaccine Inactivated contains thimerosal as a preservative at a final concentration of 0.007%. The dose for children from 12 to 35 months of age is 0.5 milliliters, which contain 17.5 micrograms of mercury. The dose for persons three years of age and older is 1.0 milliliter, which contain 35 micrograms of mercury. The mercury content of Japanese Encephalitis Virus Vaccine Inactivated exceeds the limit set by California Health and Safety Code section 124172 subdivision (a) of 0.5 micrograms of mercury per 0.5 milliliter dose for vaccines (other than influenza vaccine) administered to young children and pregnant women in California on or after July 1, 2006. The bill that created this law, AB 2943 (Pavley, Chapter 837, Statutes of 2004), was signed in 2004 by Governor Arnold Schwarzenegger to ensure that pregnant women and children younger than age three years of age have access to mercury-free vaccines.

2) Japanese Encephalitis Vaccine, Inactivated, Adsorbed whose trade name is IXIARO®. It is manufactured in England by Intercell Biomedical and distributed in the United States by Novartis Vaccines and Diagnostics, Inc. This vaccine was licensed by FDA in March 2009 for use in persons 17 years of age and older. It is free of preservatives, including those that contain mercury.

The federal Advisory Committee on Immunization Practices recommends that JE vaccine be offered to travelers who plan to spend a month or longer in endemic areas during the JE virus transmission season. This includes longer-term travelers, recurrent travelers, or expatriates who will be based in urban areas but are likely to visit endemic rural or agricultural areas during a high risk period of transmission. JE vaccine is also recommended for laboratory personnel who work with live, wild-type JE virus strains.

JE vaccine should be considered for travelers

- of less than one month to endemic areas during the transmission season if they plan to travel outside of an urban area and have an increased risk of exposure
- to an area with an ongoing JE virus outbreak
- to endemic areas who are uncertain of their destinations, activities, or duration of travel.

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JE vaccine is not recommended for short-term travelers whose visit will be restricted to urban areas or times outside of a well-defined transmission season.

For more information on the recommended use of JE vaccine, please see <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.

Exemption to California Mercury Free Vaccine Act

California Health and Safety Code section 124172 subdivision (c) permits the Secretary of the California Health and Human Services Agency to exempt the use of a vaccine from section 124172 subdivision (a) “if the secretary finds, and the Governor concurs, that...shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant receiving the needed vaccine,” making “necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)...” (<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=124001-125000&file=124172>)

Because of the dangers posed by JE virus to those residing or traveling in affected areas, and because there is no alternative vaccine for Californians younger than 17 years of age seeking protection against JE virus, an exemption has been granted again from California Health and Safety Code section 124172 subdivision (a) for Japanese Encephalitis Virus Vaccine Inactivated for the period of July 1, 2010, through June 30, 2011. This vaccine may continue to be administered, as permitted by other State and federal laws, to children younger than 3 years old and women who are pregnant and younger than 17 years old.

For additional information about this topic, please contact the California Department of Public Health Immunization Branch at (510) 620-3737 or www.getimmunizedca.org.

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators